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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/532,384	09/22/95	ARTAVANIS-TSAKUNAS	7326-035

18M1/1202

PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

EXAMINER
EYLER, Y

ART UNIT	PAPER NUMBER
1806	

DATE MAILED: 12/02/97

12/02/97
10

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/532,384

Applicant(s)

Artavanis-Tsakonas

Examiner

Yvonne Eylar

Group Art Unit

1806



☒ Responsive to communication(s) filed on Aug 27, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ~~7 months~~ or thirty days, ~~which ever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 90-123 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 90-123 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's response, filed on 8/27/97 as paper no. 9, is acknowledged, however, upon further consideration restriction to one of the following inventions is required under 35 U.S.C. 121 as follows:

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 90, 92, 98, 101, 103-106, and 109-112, drawn to a method of manipulating cell differentiation by promoting Notch function, classified in 424, subclass 130.1+.
 - II. Claims 90, 91, 93-97, 99-102, 104, 106-109, and 112 drawn to a method of manipulating cell differentiation by antagonizing Notch function, classified in class 424, subclass 130.1+.
 - III. Claims 113-123, drawn to methods of manipulating cell differentiation by interfering with toporythmic protein binding, classified in class 424, subclass 130.1+.

The Groups have been rearranged as suggested by applicant at page 3 of the response filed 8/27/97. Group I is drawn to methods of promoting Notch function while Group II is drawn to methods of antagonizing Notch function. Group III is drawn to methods of manipulating toporythmic protein binding. Groups I and II differ in whether the method promotes or antagonizes Notch function. The inventions differ in that they are drawn to two entirely different methods using different reagents and having different outcomes. A reagent which promotes Notch activity does not antagonize Notch activity. Applicant argues that it would not be a serious burden to search the groups together and that they should not be divided because they are all

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classified in the same class and subclass. This is not found to be persuasive because the two groups are related only as therapeutic methods. They are however, drawn to entirely different, divergent subject matter which requires different searches. The search for promoters of Notch function does not necessitate the search for antagonists and the inhibition of cell growth as does the second group. With regard to the new third Group, claims 113-123 were originally grouped with the inventions of Groups I and II, however, the claimed methods do not necessarily promote or antagonize Notch function. Upon closer inspection, the methods seem to be drawn to interfering with any binding interactions occurring between Notch, Delta, and Serrate, or any other toporythmic protein, irregardless of Notch function. For example, the claims encompass Delta as first and second proteins or Delta plus some other toporythmic protein. Thus, upon further consideration, the methods of Group III are found to be drawn to entirely different methods than those of Groups I and II because they involve different reagents and different outcomes which do not affect Notch function.

2. Because these inventions are distinct for the reasons given above and the search required for each Group is not required for any other Group, restriction for examination purposes as indicated is proper.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A) The invention of Group I is further directed to the following species:

a) methods using the toporythmic Delta protein or fragments of Delta protein.

(Claims 98, 103, 106, 109, 110)

b) methods using intracellular Notch protein fragments (Claims 98, 101, 104, 106, 109, 112)

c) methods using the toporythmic protein Serrate (98, 105, 106, 109, 111)

These species are found to be different because they involve different proteins with totally different biochemical structures and functions and the search for one protein is not required for the search of another.

B) The invention of Group II is further directed to the following species:

a) methods using Notch protein or extracellular protein fragments (90, 91, 93, 99, 100, 101, 104, 107, 108, 109, 112)

b) methods involving antibodies to Notch (90, 91, 94, 95, 96, 107, 108, 120-123)

c) methods involving antibodies to Delta (90, 91, 94,95, 97, 107, 120-123)

d) methods involving antibodies to Serrate (90, 91, 94,95, 97, 107, 120-123)

e) methods involving antisense (90, 91, 102, 107)

f) methods involving Notch sense DNA (90, 91, 106, 107)

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The species claimed are each drawn to molecules which are entirely different biochemically and functionally.

Note that claims 94-97 drawn to antibodies have been placed only in Group II, as antagonists because, as understood, if the toporythmic proteins Delta and Serrate are promoters, then antibodies to Delta and Serrate should be antagonists.

C)The invention of Group III is further directed to the following species:

- a) methods applying Notch and affecting binding with Notch
- b) methods applying Notch and affecting binding with Delta
- c) methods applying Notch and affecting binding with Serrate
- d) methods applying Delta and affecting binding with Notch
- e) methods applying Delta and affecting binding with Delta
- f) methods applying Delta and affecting binding with Serrate
- g) methods of applying Serrate and affecting binding with Notch
- h) methods of applying Serrate and affecting binding with Delta
- I) methods of applying Serrate and affecting binding with Serrate.

The are found to be different species because each combination recited by the claims does not involve the interruption of the other combinations of proteins.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a diligently-filed petition under 37

CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne Eyler, Ph.D. whose telephone number is (703) 308-6564. The examiner can normally be reached on Monday through Friday from 830am to 630pm.

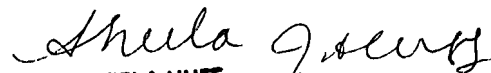
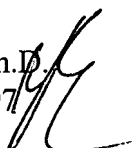
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [lila.feisee@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Yvonne Eyler, Ph.D.
December 1, 1997



**SHEELA HUFF
PATENT EXAMINER
GROUP 1800**